JAN - 6 2009

510(k) Number K082750

510(k) SUMMARY

Trade Name:	ENTact™ Septal Stapler
Sponsor:	ENTrigue Surgical, Inc. 12672 Silicon Drive, Suite 150 San Antonio, Texas 78249 Telephone: (210) 298-6336 Fax: (210) 298-6399 Contact Person: Gabriele G. Niederauer, Ph.D.
Date Prepared:	January 5, 2009
Product Code and Device Classification Name:	OLL Implantable Staple (21 C.F.R. § 878.4750)
Classification:	Class II
Predicate Devices:	Incisive Surgical, INSORB® Absorbable Staple Ethicon Inc., Vicryl® Suture
Device Description:	The ENTact™ Septal Stapler consists of resorbable fixation devices, which are delivered via an manual surgical stapler delivery system. The ENTact™ implantable septal staples, composed of an absorbable copolymer, may be used during nasal surgery to approximate the mucoperichondrial flaps of the nasal septum and at the completion of surgery. The staples are provided preloaded in a single-use, disposable stapler.
Indications for Use:	The ENTact™ Septal Stapler delivers implantable septal staples which are intended to connect internal tissues to aid healing and for approximation of soft tissues during nasal septal surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2009

ENTrigue Surgical, Inc.
c/o Gabriele G. Niederauer, Ph.D.
Vice-President, Research & Development
12672 Silicon Drive, Suite 150
San Antonio, TX 78249

Re: K082750
Trade/Device Name: ENTact Septal Stapler System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: OLL
Dated: December 19, 2008
Received: December 22, 2008

Dear Dr. Niederauer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082750

Indications for Use Statement

510(k) Number (if known): K082750

Device Name: ENTact™ Septal Stapler

Indications for Use:

The ENTact™ Septal Stapler delivers implantable septal staples which are intended to connect internal tissues to aid healing and for approximation of soft tissues during nasal septal surgery.

Prescription Use ☒ AND/OR Over-The-Counter Use ☐

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel C Clark

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K082750